PRESCRIBING INFORMATION (PI):

▼ **Panzyga®** (human normal immunoglobulin, IVIg)

Presentation:
Solution for infusion containing 100 mg/mL human normal immunoglobulin of which ≥95% is IgG. IgA content ≤0.3 mg/mL

Indications and Dosages:
Primary immunodeficiency syndromes: Starting dose 0.4-0.8 g/kg followed by 0.2-0.8 g/kg every 3-4 weeks.
Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia, in whom prophylactic antibiotics have failed or multiple myeloma patients who have failed to respond to pneumococcal immunisation:
0.2-0.4 g/kg every 3-4 weeks.
Hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation (HSCT). Congenital AIDS with recurrent bacterial infections: 0.2-0.4 g/kg every 3-4 weeks.
Primary immune thrombocytopenia (ITP): 0.8-1 g/kg on day 1, possibly repeated once within 3 days, or 0.4 g/kg/day for 2-5 days.
Guillain Barré syndrome: 0.4 g/kg/day over 5 days.
Kawasaki disease: 1.6-2 g/kg in divided doses over 2–5 days or 2 g/kg as a single dose, both with concomitant aspirin.

Method of Administration:
Intravenous infusion only, at initial rate of 0.6 mL/kg/hr for 30 minutes. If well tolerated, increase gradually to maximum of 4.8 mL/kg/hr. In PID patients who tolerate this maximum rate well, the rate may be further increased gradually to 8.4 mL/kg/hr.

Contraindications:
Hypersensitivity to active substance or to any of the excipients. Hypersensitivity to human immunoglobulins, especially in patients with antibodies against IgA.

Special Warnings and Precautions:
Certain reactions may occur more frequently with high infusion rate, treatment-naive patients, or in rare cases when the IVIg is switched or there has been a long interval since the previous infusion. In case of adverse reaction, rate of administration must be reduced or infusion stopped. All patients should be adequately hydrated prior to infusion. Avoid concomitant use of loop diuretics.
Hypersensitivity: They can occur in patients with anti-IgA antibodies. Rarely, IVIg can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment.
Thromboembolism: In patients with pre-existing thromboembolic risk factors IVIg products should be administered at the minimum rate of infusion and dose practicable. Acute renal failure: Cases of acute renal failure have been reported in patients receiving IVIg therapy especially where pre-existing risk factors exist. In patients at risk for acute renal failure, IVIg products should be administered at the minimum rate of infusion and dose practicable.
Aseptic meningitis syndrome (AMS): AMS has been reported to occur in association with IVIg treatment and may occur more frequently in association with high-dose (2 g/kg) IVIg treatment. Haemolytic anaemia: IVIg may contain blood group antibodies, causing haemolysis. Monitor for signs and symptoms. Transmissible agents: Risk of transmitting infective agents cannot be totally excluded – record patient name and product batch number. Sodium content: ≤0.03 mmol/mL.
Interference with serological testing: Passive immunity from IVIg administration can reduce the effectiveness of live attenuated virus vaccines for up to 1 year in some cases. Passive transmission of antibodies may interfere with some serological tests

Undesirable Effects:
Common (≥1/100 to <1/10): headache; nausea; pyrexia. Uncommon (≥1/1,000 to <1/100): haemolysis; anaemia; leukopenia; aseptic meningitis; tachycardia; hypertension; hepatic enzyme increased; Rare (≥1/10,000 to <1/1,000): sudden fall in blood pressure; anaphylactic shock; haemolytic anaemia; Very rare (<1/10,000): thromboembolic reactions such as myocardial infarction, stroke, pulmonary embolism, deep vein thrombosis. Not known (cannot be estimated from available data): increase in serum creatinine; acute renal failure; pancytopenia; hypersensitivity; anaphylactic reaction; anaphylactoid reaction; cerebrovascular accident; coma; loss of consciousness; convulsion; encephalopathy; cardiac arrest; angina pectoris; bradycardia; cyanosis; peripheral circulatory failure or collapse; respiratory failure; apnoea; acute respiratory distress syndrome; pulmonary oedema; bronchospasm; dyspnoea; hypoxia; Steven-Johnson syndrome; epidermolysis; urticaria; (bullous) dermatitis; osmotic neuropathy; transfusion related acute lung injury (TRALI). Consult the Summary of Product Characteristics in relation to other adverse reactions.

Legal Category: POM

Pack Sizes and Basic NHS cost:
1 g in 10 mL £58.65; 2.5 g in 25 mL £146.63; 5 g in 50 mL £293.25; 10 g in 100 mL £586.50; 20 g in 200 mL £1,173.00; 30 g in 300 mL £1,759.50.

Marketing Authorisation Number: PL 10673/0042

Marketing Authorisation Holder: Octapharma Ltd, The Zenith Building, 26 Spring Gardens, Manchester, M2 1AB, United Kingdom.

PI Reference: P.820.001.UK

Date of last revision: AUG-2018

Reporting of side effects
Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Octapharma by telephoning 0845 1300 522.